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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,586	05/02/2001	Victor V. Gogolak	597932000200	6777

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EXAMINER	
BUSS, BENJAMIN J	

ART UNIT	PAPER NUMBER
2129	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/681,586	GOGOLAK, VICTOR V.	
	Examiner	Art Unit	
	BENJAMIN BUSS	2129	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/10/02, 10/9/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to patent application 09/681,585 filed on **5/2/2001**. Claims 1-28 are pending.

Information Disclosure Statement

The information disclosure statement filed 9/10/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. **No copy of the following document has been found in the file:**

- "VAERS Data: Guide to Interpreting Case Report Information Obtained From the Vaccine Adverse Event Reporting System (VAERS)" ... 2002, 2 pp., ...

The information disclosure statement filed 9/10/2002 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. **No English translation or concise explanation of the relevance of the following documents has been found in the file:**

- JP11-282934
- JP10-225500

Drawings

The drawings are objected to because Figures 1-21 are illegible and the text is not readable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are

not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: The application number referenced in ¶[0104] of the instant application, as filed, needs to be filled in. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-8, 15, and 17-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 15-26 of U.S. Patent No. 7,542,961. Although the conflicting claims are not identical, they are not patentably distinct from each other because the person of ordinary skill in the art at the time the invention was made would have found it obvious for the display of the correlated results in U.S. Patent No. 7,542,961 to be in a format that permits perception of correlations.

Claims 1, 6, 15, and 20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8, and 27 of U.S. Patent No. 7,461,006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the person of ordinary skill in the art at the time the invention was made would have found it obvious for the display of the correlated results in U.S. Patent No. 7,461,006 to be in a format that permits perception of correlations.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1 and 15 recite the limitation "the risks of adverse effects" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. **Consider deleting "the", thereby providing proper antecedent basis for subsequent uses of this phrase.**
- Claims 1 and 15 recite the limitation "the use" in line 2. There is insufficient antecedent basis for this limitation in the claim. **Consider deleting "the", thereby providing proper antecedent basis for subsequent uses of this phrase.**
- Claims 1 and 15 recite the limitation "the profile" in line 4. There is insufficient antecedent basis for this limitation in the claim.
- Claims 1 and 15 recite the limitation "the safety" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.
- Claims 1 and 15 recite the limitation "the results" in line 8. There is insufficient antecedent basis for this limitation in the claim.
- Claims 3, 4, 17, and 18 recite the limitation "the reactions" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.
- Claims 5 and 19 recite the limitation "characteristics in drug/reaction/demographic information" in line 4. The intended meaning of this phrase is not clear. Examiner interprets the phrase to mean "involving at least one of: drug information, reaction information, and demographic information", in which the claim is met if at least **one** of the three alternatives is present in the prior art.
- Claims 16-28 recite the limitation "the use of the drug of interest" in line 2. There is insufficient antecedent basis for this limitation in the claim. **Change claim 16 to depend upon claim 15 to resolve this issue.**
- Claims 2 and 6-14 are rejected by virtue of their dependence on a rejected base claim.

Appropriate corrections are required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-20, and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Szarfman** ("New Methods for Signal Detection"). ***Examiner notes that the prior art being mapped to a "drug of interest" also therefore covers a "substance of interest", as a drug is a substance.***

Claims 1 and 15: Szarfman teaches:

- identifying the at least one drug of interest (p1-56 especially "Detection of 'higher than expected' signal scores" p23 or "data extraction" p32 or "scores … associated with a specific drug" p48);
- selecting [a] profile of the at least one drug of interest related to [] safety of the at least one drug of interest, using at least one filter (p1-56 especially "Drug-event combinations by drug, drug class, event, event group, and time interval" p23 or "stratification" p28 or "age specific exposure" p30 or "derived from application of a statistical model to identify the ones observed at higher than expected frequencies" p32);
- analyzing the risks of adverse effects resulting from the use of the at least one drug of interest using at least one data mining engine (p1-56 especially "Data Mining" p23 or "identifying and documenting many serious rare adverse drug reactions" p26 or "gender-based patterns" p29 or "estimate SS" p32 or "model ***DERIVED*** from the data" p42); and
- displaying [] results of the analysis of risks of adverse effects resulting from the use of the at least one drug of interest in a format that permits perceptions of correlations (p1-56 especially p16 or p18 or 21 or p23 or p32 or "each distinct combination of any drug, event, sex, time, and age group" p35 or p42-43 or p46-52 or "predict patients at risk" p56).

Claims 2 and 16: Szarfman teaches: wherein the format is at least one format selected format he group consisting of a radar display for display of correlations (p1-56 especially p15-16 or p47 or p49 or p52), a sortable table (p1-56 especially p17-18 or p21 or p36-37 or p44 or p46 or p48), and a sortable line listing (p1-56 especially p17-18 or p21 or p36-37 or p44 or p46 or p48).

Claims 3 and 17: Szarfman teaches: wherein the at least one data mining engine is a proportional analysis engine to assess deviations in a set of the reactions to the at least one drug of interest (p1-56 especially p43 or p48).

Claims 4 and 18: Szarfman teaches: wherein the at least one data mining engine is a comparator to measure [] reactions to the at least one drug of interest against a user-defined backdrop (p1-56 especially p51 or p53).

Claims 5 and 19: Szarfman teaches: wherein the at least one data mining engine is a correlator to look for correlated signal characteristics in at least one of drug information, reaction information, and demographic information (p1-56 especially p23 or p32 or p35 or p42 or p49).

Claims 6 and 20: Szarfman teaches: wherein the data mining engine is at least two members of the group consisting of: a proportional analysis engine (p1-56 especially p43 or p48), a comparator (p1-56 especially p51 or p53), and a correlator (p1-56 especially p23 or p32 or p35 or p42 or p49).

Claims 8 and 22: Szarfman teaches: wherein the method permits assessment and analysis of the risks of adverse effects resulting from the use of at least one drug of interest in any of multiple dimensions of the risk assessment and analysis (p1-56 especially p32 or p42 or p49).

Claims 9 and 23: Szarfman teaches: wherein the format is a radar display for display of correlations (p1-56 especially p15-16 or p47 or p49 or p52).

Claims 10 and 24: Szarfman teaches: wherein the radar display contains elements linked to data regarding the adverse effects (p1-56 especially p15-16 or p47 or p49 or p52).

Claims 11 and 25: Szarfman teaches: wherein the format is a sortable table (p1-56 especially p17-18 or p21 or p36-37 or p44 or p46 or p48).

Claims 12 and 26: Szarfman teaches: wherein the sortable table contains elements linked to data regarding the adverse effects (p1-56 especially p17-18 or p21 or p36-37 or p44 or p46 or p48).

Claims 13 and 27: Szarfman teaches: wherein the format is a sortable line listing (p1-56 especially p17-18 or p21 or p36-37 or p44 or p46 or p48).

Claims 14 and 28: Szarfman teaches: wherein the sortable line listing contains elements linked to data regarding the adverse effects (p1-56 especially p17-18 or p21 or p36-37 or p44 or p46 or p48).

Claim Rejections - 35 USC § 103

Claims 7 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Szarfman** ("New Methods for Signal Detection") and **Classen** (USPN 6,219,674).

Claims 7 and 21:

Szarfman teaches:

- wherein the at least one substance of interest is assessed in combination with other drugs, chemicals, and hormones (p1-56 especially i.e. pages 23, 32, 35, 38, 42, or 50).

Szarfman fails to teach:

- wherein the substance of interest is assessed in combination with foodstuffs, beverages, nutrients, vitamins, toxins, and supplements.

Classen teaches:

- wherein the at least one substance of interest is assessed in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements (C1-12 especially i.e. C5L10-18 or C6L9-30 or C6L55-C7L25).

Rationale:

Szarfman and **Classen** are from the same field of endeavor, detecting adverse effects of drugs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of **Szarfman** by assessing the substance of interest in combination with other drugs, foodstuffs, beverages, nutrients, vitamins, toxins, chemicals, hormones, and supplements as taught by **Classen** for the benefit of identifying new uses or restrictions for medical products (**Classen** C3L13-21).

Conclusion

Claims 1-28 are rejected.

Correspondence Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN BUSS whose telephone number is (571)272-5831. The examiner can normally be reached on at least Monday, Tuesday, Thursday, or Friday 9AM-5PM.

As detailed in MPEP 502.03, communications via Internet e-mail are at the discretion of the applicant. Without a written authorization by applicant in place, the USPTO will not respond via Internet e-mail to any Internet correspondence which contains information subject to the confidentiality requirement as set forth in 35 U.S.C. 122. A paper copy of such correspondence will be placed in the appropriate patent application. The following is a sample authorization form which may be used by applicant:

> "Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Vincent can be reached on 571-272-3080. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Benjamin Buss
Examiner
Art Unit 2129

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